

may also satisfy data requirements in this part. Consultation with the Agency should be arranged if applicants are unsure about suitability of such data.

Subpart B—How To Use Data Tables

§ 158.100 Pesticide use patterns.

(a) *General use patterns.* There are six broad use categories used in the data tables. The six broad categories include terrestrial outdoor uses, aquatic outdoor uses, greenhouse uses, forestry uses, residential outdoor uses, and indoor uses of all types. The 6 broad use categories are further subdivided into 12 general use patterns which are the bases for data requirements established by use pattern. Within the data tables, general use patterns have been combined into single columns when the data requirements are the same for the combined uses. If there are no data requirements for a specific use, the column for that use is not included in the table. The 12 general use pattern groups used in the data table in this part are:

- (1) Terrestrial food crop use.
- (2) Terrestrial feed crop use.
- (3) Terrestrial nonfood crop use.
- (4) Aquatic food crop use.
- (5) Aquatic nonfood use.
- (6) Greenhouse food crop use.
- (7) Greenhouse nonfood crop use.
- (8) Forestry use.
- (9) Residential outdoor use.
- (10) Residential indoor use.
- (11) Indoor food use.
- (12) Indoor nonfood use.

(b) *Pesticide use site index.* The Pesticide Use Site Index is a comprehensive list of specific pesticide use sites. The index is alphabetized separately by site for all agricultural and all non-agricultural uses. The Pesticide Use Site Index associates each pesticide use site with one or more of the 12 general use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be obtained from the Agency's website at <http://www.epa.gov/pesticides>.

(c) Applicants unsure of the correct use pattern for their particular product should consult the Agency.

§ 158.110 Required and conditionally required data.

The tables in this part use the descriptors R (required), CR (conditionally required), and NR (not required) as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

(a) EPA requires data designated as “required” (R) for products with a given use pattern in order to evaluate the risks or benefits of a product having that use pattern under any conditions established by the test notes.

(b) Data designated as “conditionally required” (CR) for products with a given use pattern are required by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the notes accompanying the requirement. The determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (for example, tier testing). Applicants must evaluate each applicable test note for the conditions and criteria to be considered in determining whether conditionally required data must be submitted.

(c) Data not required for the Agency's assessment of the risks and benefits of a particular use pattern are designated “not required” (NR) in data tables.

§ 158.120 Determining data requirements.

As with current practice, the actual data and studies required may be modified on an individual basis to fully characterize the use and properties of specific pesticide products under review. While EPA is attempting to assist the applicant in this subpart, it is important to emphasize that it is the applicant's obligation under FIFRA to demonstrate that an individual product meets the standard under FIFRA and/or FFDCA. Accordingly, applicants are

encouraged to consult with the Agency on the appropriate data requirements as set forth here as they relate to their specific product prior to and during the registration process.

(a) *Finding the appropriate data table.*

(1) Pesticide data requirements for conventional chemical active ingredients and related substances are presented in subparts D, E, F, G, K, L, N, and O of this part in the form of a series of data tables, each addressing a particular scientific discipline or data topic. Data requirements for biochemical and microbial pest control agents are contained and are described separately within subparts U and V of this part, respectively.

(2) Key to table notations. R = required data; CR = conditionally required data; NR = Not required; MP = manufacturing-use product; EP = end-use product; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = pure active ingredient; PAIRA = pure active ingredient, radiolabeled; Choice = choice of several test substances depending on studies required.

(b) *Identifying required studies.* To determine the specific kinds of data needed to support the registration use of each pesticide product, the applicant may:

(1) Refer to the applicable subpart(s) of this part. These subparts describe the data requirements including data tables for each subject area.

(2) Select the general use pattern(s) that best cover the use pattern(s) specified on the pesticide product label as explained in § 158.100. All applicable use patterns must be included.

(3) Proceed down the appropriate general use pattern column in the table and note which tests are required (R), conditionally required (CR), or not required (NR). Required and conditionally required studies are described in § 158.110.

(4) Review the notes for each requirement to determine its applicability to the specific product proposed for registration.

(5)(i) Proceed down the Test substance columns and determine the appropriate test substance needed for that study. If the data are intended to support a manufacturing-use product,

use the MP column. If the data are intended to support an end-use product, use the EP column.

(ii) The test substances columns specify which substance is to be used for testing. Applicants should note that the substance that must be used when performing the study may or may not be the product itself. For example, the data from a certain study may be required to support the registration of an end-use product, but the test substance column may state that the particular test shall be performed using the technical grade of the active ingredient(s) in the end-use product.

(iii) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no intentionally added inert ingredients are considered identical in composition to each other, and to the technical grade of the active ingredient (TGAI) from which they were derived. Therefore, the data from a test conducted using any one of these as the test substance is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances.

(6) Refer to the Pesticide Assessment Guideline reference number for each study located in the first column. See § 158.70(c) for information pertaining to the guidelines and how to obtain copies.

§ 158.130 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) *Product chemistry*—(1) *Product composition.* Data on product composition are needed:

(i) To support the conclusions expressed in the statement of formula;

(ii) To compare to the composition of materials used in required testing under this part; and

(iii) To determine whether a product is “identical or substantially similar” to another product, a determination that involves the comparison of product composition.